I. The Office Action

The February 3, 2009 Final Office Action (the "Office Action") in this application:

1.) rejects claims 1-6, 8-10 and 12-21 under 35 U.S.C. 102(e); and

2.) rejects claims 1-6, 8-10 and 12-24 under 35 U.S.C. 112, first paragraph.

Applicant requests a three-month extension of time to reply to the Office Action, requests continued examination (RCE) and replies to the outstanding rejections as follows.

II. Rejection of claims 1-6, 8-10 and 12-21 under 35 U.S.C. 102(e)

The Office Action rejects claims 1-6, 8-10 and 12-21 under 35 U.S.C. 102(e) as being anticipated by Kwon Published U.S. Patent Application 2004/0087893, as evidenced by Allergan (pages 1-4, http://www.allergan.com/download/BotoxPL.pdf, accessed on March 22, 2007) for the reasons set forth in the previous Office Action. Applicant respectfully traverses this rejection.

As previously pointed out and well known, the law is clear that in order to anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 224 USPQ 409, 411 (Fed. Cir. 1984). Moreover, the single source must disclose all of the claimed elements "arranged as in the claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983).

Recent support and clarification of the correct standard of law was provided by the Federal Circuit that, for a prior art reference to anticipate a claim, each and every claimed element must be "arranged and combined in the same way" in the prior art reference. (*Net MoneyIN, Inc. v. VeriSign, Inc.*, No. 2007-1565 at 8 (Fed.Cir. Oct. 20, 2008)).

For the Office Action's anticipation rejection to stand, the Office Action is asserting that each and every claimed element recited in the instant claim are not only found in Kwon, but are also arranged and combined in the same way. This is simply not the case.

Previously provided evidence by Applicant clearly shows that the interpretation of term "needle" as asserted by the Office Action, is not a reasonable broadest interpretation in light of the pertinent facts. The Office Action cannot simply disregard the statements previously presented and made in Kwon's disclosure, as well as during prosecution of that cited reference, that makes it explicitly clear that Kwon does not identically disclose administration of botulinum toxin with a needle as now claimed.

Kwon stated in paragraph [0077] that in "contrast to conventional hollow needle technologies, the SSP system includes a solid matrix of dissolvable (including meltable) or biodegradable material that optionally holds one or more selected drugs and is formed into one or more perforators." (Emphasis added). Further, during prosecution, Kwon responded to an Office action dated June 1, 2004 with an amendment submitted on August 27, 2004. The submitted remarks therein clearly show that Kwon's disclosure **excludes** delivery of botulinum toxin with a needle:

> Neither Melone or Eicher teach or suggest an array of **dissolvable perforators** as claimed. As explained throughout the present application, the salient feature of applicant's invention is that the perforators used to pierce or otherwise make channels in the skin are **themselves dissolvable**. The matrix used to form the perforators is made of the drug to be delivered and/or of a soluble material that quickly dissolves after insertion into the skin. This technology is quite distinct from hollow needle technologies and the like, that use microneedles and other injection devices made from materials such as metals and polymers that do not dissolve upon contact with the skin. For example, Melone uses metal plates with needlelike projections that are coated with the desired substance. There is no disclosure in Melone regarding dissolvable perforators. Similarly, Eicher uses micro-pins with capillary openings to deliver the active substance. Although Eicher states that the pins can be made from biodegradable polymers, the biodegradable polymers described do not dissolve within seconds or hours as claimed. Moreover, Eicher's micro-pins do not include a drug incorporated therein. Thus, Melone and Eicher do not teach each and every element of the claimed invention and therefore cannot anticipate the present claims. (Emphasis Original, Page 10, ¶3, Kwon's Amendment dated August 27, 2004).

> However, as with Melone and Eicher above, Lastovich nowhere describes dissolvable **perforators** as claimed. Rather, Lastonvich uses microneedles or the like to perforate the skin and drug is either delivered through a central channel in the needle or is coated onto the outside of the needle. (Emphasis Original, Page 11, ¶1, Kwon's Amendment dated August 27, 2004).

As one of ordinary skill in the art can plainly see from the above excerpt and also from Kwon's own disclosure, Kwon not only fails to anticipate the present claims by falling short of identical disclosure, but actively and takes the step of excluding the currently introduced element: "...with a needle..." The prior art is replete with examples of botulinum toxin administration utilizing needles, and indeed and as evidenced by Kwon, this is precisely the technology that Kwon (as shown above) plainly and specifically is designed to overcome, as shown in the specification of Kwon, where it is stated that in "contrast to conventional hollow needle technologies, the SSP system includes a solid matrix of dissolvable (including meltable) or biodegradable material that optionally holds one or more selected drugs and is formed into one or more perforators."

The Office Action asserts that "...at the point of administration the botulinum toxin is in a solution form, which is indicative of a liquid solution." (Office Action, page 4, lines 12-14). It unclear as to what/how this conclusory statement meets the instantly claimed limitations of administering a liquid solution comprising a botulinum toxin. Such conclusory statements are untenable and it seems that the Office Action is attempting to assert that this claimed limitation is inherently met by Kwon. However, according to MPEP 2112, "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

The same can be said of the Office Action's assertions that Kwon meet the limitation of administration of botulinum toxin in an amount less than that used to paralyze a muscle. This phrase simply does not appear in Kwon's specification, and as is well known "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however,

may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted). Kwon's disclosure does not disclose the instant pending limitation.

Thus, simply and when the instant claims are interpreted in light of the clear and unmistakable disclosure and arguments, made by Kwon, that Kwon's disclosure does not teach the use of needles to inject solutions, each and every element of the present claims cannot anticipated by this reference. Thus this rejection should be withdrawn.

III. Rejection of claims 1-6, 8-10 and 12-24 under 35 U.S.C. 112, first paragraph)

The Office Action rejects claims 1-6, 8-10 and 12-24 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection.

Respectfully, it is pointed out in accordance with MPEP 2163(I)(B), that there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. Respectfully and as previously pointed out, paragraph (0044) is replete with U.S. Patents/Applications related to the botulinum toxin arts, and are incorporated by reference into the instant disclosure that give a good impression of the known method of needle administration of botulinum toxin.

The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed (see, e.g., *Wang Labs. v. Toshiba Corp.*, 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993)) and should include a determination of the field of the invention and the level of skill and knowledge in the art.

Accordingly and for example, injection of botulinum toxin with a needle is known in the art. It is noted that an Applicant need not disclose in detail, and preferably omits, that which is conventional or well known in the art. (*MPEP* § 2163(II)(A)(2)), and administration/injection of botulinum toxin to a patient with a needle, is well known, as evidenced in, for example (referenced and incorporated into paragraph 0044 of the instant published specification), in USP 6458365, col. 5, lines 10-19, where "Before injecting any muscle group, careful consideration is given to the anatomy of the muscle group, the aim being to inject the area with the highest concentration of neuromuscular junctions, if known. Before injecting the muscle, the position of the needle in the muscle is confirmed by putting the muscle through its range of motion and observing the resultant motion of the needle end. General anaesthesia, local anaesthesia and sedation are used according to the age of the patient, the number of sites to be injected, and the particular needs of the patient. More than one injection and/or sites of injection may be necessary to achieve the desired result. Also, some injections, depending on the muscle to be injected, may require the use of fine, hollow, teflon-coated needles, guided by electromyography.

Additional disclosure (referenced in paragraph 0044 of the instant published specification) from USP 5714468, col. 7, lines 18-30 states that "...use of electromyographical ("EMG") injection is recommended. A preferred technique for EMG injection is to introduce the presynaptic neurotoxin through a monopolar hollow bore needle (commonly, one which is coated with a non-stick surface such as "TEFLON", a trademarked product of DuPont Nemours, of Massachusetts). The needle is placed through the skin and into the target site of a muscle, preferably at a neuromuscular junction. Once the needle has been inserted, the most active site of the muscle can be determined by observation of the EMG signal. Those of ordinary skill in the art will know of, or can readily ascertain, other suitable techniques for administering EMG injections."

It is pointed out that this information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. *Id.* Replacing the identified material

incorporated by reference with another is not new matter. *Id.* Thus, recitaiton of "injection with a needle" is not new matter and this rejection should be withdrawn.

IV. Conclusion

All issues raised in the final Office Action have been addressed and the application is believed to be in condition for allowance. A notice of allowance for pending claims 1-6, 8-10, and 12-24 is respectfully requested.

The Commissioner is hereby authorized to charge any fees required or necessary for the filing, processing or entering of this paper, including a 3-month extension of time to reply to the outstanding Office Action and a request for continued examination (RCE) fee, or any of the enclosed papers and to refund any overpayment to deposit account 01-0885.

Respectfully submitted,

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